NOV 2 9 2001 3

12-03-0

# E USTTED STATES PATENT AND TRADEMARK OFFICE

In re:

Mixson, J.A.

Examiner:

Serial No.:

Not Yet Assigned

Art Unit:

Filed:

Concurrently Herewith

Docket No.: 5627.6

For:

Carrier nucleic acids complexes containing nucleic acids encoding anti-angiogenic peptides and their use in gene therapy

U.S. Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

"Express Mail" mailing label number EL878195139 US

Date: November 28, 2001

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BY: Horshall Morshall

# PRELIMINARY AMENDMENT

Please amend the above-referenced application before action as follows:

Amendments to the Specification

Please replace the paragraph spanning pages 18-19 with:

The plasmid vector may contain multiple promotors to enhance expression efficiency. Moreover, a plasmid vector may include IRES sequence (internal ribosome entry site) between different DNA coding sequences, allowing for the translation of more than one peptide from the same transcript. Coding sequences can be associated with secretory sequences in the vector to enhance expression levels. In another embodiment of the invention, the vector may comprise an extrachromosomal replicating vector. See, e.g. Calos, TIG 12:463 (1996). In a further embodiment, RNA carries the coding sequence of antiangiogenic genes. These and other techniques to optimize expression are known to those in the art.

A marked up version of the amended paragraph is found attached at APPENDIX 1, with additions underlined and deleted text in brackets.

## Amendments to the Claims

Please cancel claims 1-20.

#### Please add claims 21-35 as follows:

- 21. A method for inhibiting tumor growth in a subject bearing a tumor, which comprises administering to the subject RNA encoding at least one anti-angiogenic protein or peptide in a carrier whereby the RNA is expressed and tumor growth is inhibited, wherein the carrier is selected from the group consisting of lipsomes, cationic polymers, micelles or combinations of such carriers.
- 22. The method of claim 21, wherein the injection is intravenous injection.
- 23. The method of claim 21, wherein the carrier is a liposomal carrier.
- 24. The method of claim 21, wherein the carrier is a cationic polymer carrier.
- 25. The method of claim 21, wherein the carrier is a micelle carrier.
- 26. A method for providing anti-angiogenic therapy to a subject in need thereof, which comprises administering by injection to the subject RNA encoding at least one anti-angiogenic protein or peptide in a carrier whereby the RNA is expressed and angiogenic growth is inhibited, wherein the carrier is selected from the group consisting of lipsomes, cationic polymers, micelles or combinations of such carriers.
- 27. The method of claim 26, wherein the injection is intravenous injection.
- 28. The method of claim 26, wherein the injection is injection into the tumor.
- 29. The method of claim 26, wherein the carrier is a liposomal carrier.
- 30. The method of claim 26, wherein the carrier is a cationic polymer carrier.
- 31. The method of claim 26, wherein the carrier is a micelle carrier.
- 32. The method of claim 21, further comprising administering nucleic acid encoding a tumor suppressor protein.
- 33. The method of claim 32, wherein the tumor suppressor protein is p53.
- 34. The method of claim 26, further comprising administering nucleic acid encoding a tumor suppressor protein.
- 35. The method of claim 34, wherein the tumor suppressor protein is p53.



## **REMARKS**

Claims 1-20 are replaced before action with claims 21-35, drawn to RNA embodiments.

The specification is amended to insert the citation to the journal reference into the correct location.

A PTO 1449 is submitted with this application.

If any additional fee is required by this submission, please charge account no. 03-2775.

Respectfully submitted,

Date: 11 24 01

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Mixson, J.A. Continuation Under 1.53(b) of S.N. 09/500,838

### **APPENDIX 1**

A marked up copy of the amended paragraph spanning pages 18-19 is shown below, with additions underlined and deleted text in brackets.

The plasmid vector may contain multiple promotors to enhance expression efficiency. Moreover, a plasmid vector may include IRES sequence (internal ribosome entry site) between different DNA coding sequences, allowing for the translation of more than one peptide from the same transcript. Coding sequences can be associated with secretory sequences in the vector to enhance expression levels. In another embodiment of the invention, the vector may comprise an extrachromosomal replicating vector. See, e.g. Calos, TIG 12:463 (1996). In a further embodiment, RNA carries the coding sequence of antiangiogenic genes. [See, e.g. Calos, TIG 12:463 (1996).] These and other techniques to optimize expression are known to those in the art.